

Appl. No. : 09/916,711  
Filed : July 27, 2001

### AMENDMENTS TO THE CLAIMS

1. (Original) A sensor head for use in an analyte measuring device comprising:
  - a) a non-conductive body;
  - b) a working electrode, a reference electrode and a counter electrode, wherein said electrodes pass through said non-conductive body forming an electrochemically reactive surface at one location on said body and an electronic connection at another location on said body, further wherein said electrochemical reactive surface of said counter electrode is greater than the surface area of said working electrode; and
  - c) a multi-region membrane affixed over said non-conductive body and covering said working electrode, reference electrode and counter electrode.
2. (Previously presented) A sensor head for use in an implantable analyte measuring device comprising:
  - a) a non-conductive body suitable for implantation in a host;
  - b) a working electrode, a reference electrode and a counter electrode, wherein said electrodes pass through said non-conductive body forming an electrochemically reactive surface at one location on said body and an electronic connection at another location on said body, further wherein said electrochemical reactive surface of said counter electrode is greater than the surface area of said working electrode; and
  - c) a multi-region membrane affixed over said non-conductive body and covering said working electrode, reference electrode and counter electrode.
3. (Original) A sensor head according to claim 1 wherein said multi-region membrane comprises an oxygen antenna domain.
4. (Original) A sensor head according to claim 2 wherein said multi-region membrane comprises an oxygen antenna domain.
5. (Original) A sensor head according to claim 2 wherein said multi-region membrane comprises a first region distant from said electrochemically reactive surfaces, a second region less distant from said electrochemically reactive surfaces and a third region adjacent to said electrochemically reactive surfaces.
6. (Original) A sensor head according to claim 5 wherein said first region comprises a cell disruptive domain distant from said electrochemically reactive surfaces and a cell impermeable domain less distant from said electrochemically reactive surfaces.

Appl. No. : 09/916,711  
Filed : July 27, 2001

7. (Original) A sensor head according to claim 5 wherein said second region is a glucose exclusion domain.

8. (Original) A sensor head according to claim 5 wherein said third region comprises an immobilized enzyme domain distant from said electrochemically reactive surfaces, an interference domain less distant from said electrochemically reactive surfaces than said immobilized enzyme domain and a hydrogel domain adjacent to said electrochemically reactive surfaces.

9. (Original) A sensor head according to claim 8 wherein said third region further comprises a resistance domain more distant from said electrochemically reactive surfaces than said immobilized enzyme domain.

10. (Original) A sensor head according to claim 5 wherein said first region is permeable to oxygen and glucose.

11. (Canceled)

12. (Original) A sensor head according to claim 2 wherein said multi-region membrane comprises a first region distant from said electrochemically reactive surfaces and a further region adjacent to said electrochemically reactive surfaces.

13. (Original) A sensor head according to claim 12 wherein said first region comprises a cell disruptive domain distant from said electrochemically reactive surfaces and a cell impermeable domain less distant from said electrochemically reactive surfaces.

14. (Original) A sensor head according to claim 12 wherein said further region comprises an immobilized enzyme domain distant from said electrochemically reactive surfaces, an interference domain less distant from said electrochemically reactive surfaces than said immobilized enzyme domain and a hydrogel domain adjacent to said electrochemically reactive surfaces.

15. (Original) A sensor head according to claim 14 wherein said further region further comprises a resistance domain more distant from said electrochemically reactive surfaces than said immobilized enzyme domain.

16-20. (Canceled)

21. (Original) A sensor head according to claim 2 wherein said non-conductive body is made of ceramic or glass.

Appl. No. : 09/916,711  
Filed : July 27, 2001

22. (Original) A sensor head according to claim 2 wherein said non-conductive body is made of plastic or polymer.

23. (Original) A sensor head according to claim 2 wherein said working electrode is made of platinum.

24. (Original) A sensor head according to claim 2 wherein said counter electrode is made of platinum or gold.

25. (Original) A sensor head according to claim 2 wherein said electrochemically reactive surface of said counter electrode is greater than or equal to about two times the surface area of the working electrode and is less than or equal to about 100 times the surface area of the working electrode.

26. (Original) A sensor head according to claim 2 wherein said electrode is greater than or equal to about two times the surface area of the working electrode and is less than or equal to about 50 times the surface area of the working electrode.

27. (Original) A sensor head according to claim 2 wherein said electrochemically reactive surface of said counter electrode is greater than or equal to about two times the surface area of the working electrode and is less than or equal to about 25 times the surface area of the working electrode.

28. (Original) A sensor head according to claim 2 wherein said electrochemically reactive surface of said counter electrode is greater than or equal to about two times the surface area of the working electrode and is less than or equal to about 10 times the surface area of the working electrode.

29. (Original) An implantable device for measuring an analyte in a biological fluid comprising at least one sensor head according to claim 2.

30. (Original) A method of monitoring glucose levels, comprising:

- a) providing i) a host, and ii) an implantable device according to claim 29; and
- b) implanting said device in said host.

31. (Original) A method according to claim 30 wherein said implanting is subcutaneous.

32. (Original) A method of measuring glucose in a biological fluid, comprising;

- a) providing i) a host, and ii) an implantable device according to claim 29, said sensor head being capable of accurate continuous glucose sensing; and

Appl. No. : 09/916,711  
Filed : July 27, 2001

implanting said device in said host.

33. (Original) A method according to claim 32, wherein said implanting is subcutaneous.

Appl. No. : 09/916,711  
Filed : July 27, 2001

## **SUMMARY OF INTERVIEW – AUGUST 5, 2004**

### **Exhibits and/or Demonstrations**

None.

### **Identification of Claims Discussed**

All.

### **Identification of Prior Art Discussed**

U.S. 4,871,440 ("Nagata et al."); U.S. 6,001,067 ("Shults et al."); and U.S. 5,384,028 ("Ito").

### **Proposed Amendments**

None.

### **Principal Arguments and Other Matters**

Applicants' representative argued that in the background section of Nagata et al. where it states in reference that it is sometimes necessary to have the counter electrode be larger than the working electrode, that this passage referred to an electrode system that operated on a different principle than the electrode system of Shults et al., and that therefore the references were not combinable. The Examiner tentatively agreed. The Examiner further alerted Applicants' representative to Ito, cited by the International Searching Authority in the corresponding PCT application, which discloses a three electrode system with a counter electrode larger than the working electrode.

### **Results of Interview**

The Examiner indicated that an updated search would be required.

Appl. No. : 09/916,711  
Filed : July 27, 2001

**SUMMARY OF INTERVIEW – AUGUST 24, 2004**

**Exhibits and/or Demonstrations**

None.

**Identification of Claims Discussed**

All.

**Identification of Prior Art Discussed**

U.S. 6,001,067 (“Shults et al.”) and U.S. 5,384,028 (“Ito”).

**Proposed Amendments**

None.

**Principal Arguments and Other Matters**

The relevancy of the electrode design in Ito as applied to the continuous sensor of Shults et al. was discussed.

**Results of Interview**

The Examiner indicated that further consideration of Ito would be required.